

## **REMARKS**

### **Specification**

As an initial matter, Applicant's amendment filed March 28, 2008 has been objected to under 35 U.S.C. §132(a) for introducing new matter into the application. More particularly, it is asserted that the use of the term "blade" in claim 33 is not supported by the disclosure of the originally filed application. Without acquiescing in this assertion, the Applicant has amended claim 33 to remove the term "blade" therefrom. Accordingly, it is believed that this objection has been obviated. The other amendments to claim 33 address various informalities and are not intended to limit the scope or subject matter of claim 33, nor have they added any additional subject matter to the subject application.

### **Claim Rejections – 35 U.S.C. §103**

Claims 1, 2, 4, 6, 10-16, 21, 31 and 32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,699,248 to Jackson (hereafter "Jackson") in view of U.S. Patent No. 4,274,401 to Miskew (hereafter "Miskew"); claims 3 and 5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Jackson in view of Miskew in further view of U.S. Patent No. 6,238,396 to Lombardo (hereafter "Lombardo"); and claims 7, 8, 18 and 33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Jackson in view of Miskew and in further view of U.S. Patent No. 5,980,523 to Jackson (hereafter "the '523 patent").

Despite the indication in the Office Action regarding the rejections of claim 33 as being unpatentable over the combined teachings of Jackson, Miskew and the '523 patent, the Applicant notes that no analysis or rationale is set forth in the Office Action with regard to the rejection of claim 33 as being unpatentable over the indicated combination of references. However, it appears that an analysis regarding the rejection of claim 33 based on the Jackson/Miskew combination is set forth in the Office Action. (See page 6). Accordingly, the Applicant is responding to the outstanding Office Action under the presumption that claim 33 was intended to be rejected in view of the Jackson/Miskew combination. In the event claim 33 was not intended to be rejected in this manner, the Applicant requests clarification with respect to the same so a response traversing the intended rejection of claim 33 can be submitted if appropriate.

The seminal case directed to application of 35 U.S.C. §103 is Graham v. John Deere, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). From this case, four familiar factual inquiries have resulted. The first three, determining the scope and content of the prior art, ascertaining differences between the prior art and the claims at issue and resolving the level of ordinary skill in the pertinent art, are directed to the evaluation of prior art relative to the claims of the pending application. The fourth factual inquiry is directed to evaluating evidence of secondary considerations. (See, Manual of Patent Examining Procedure §2141). From these inquiries, the initial burden is on the Examiner to establish a *prima facie* case of obviousness. For at least the following reasons, it is respectfully submitted that a *prima facie* case of obviousness has not been established in this case.

### *Arguments in Support of Patentability*

#### *Independent Claim 1 and Dependent Claims 2-5, 7-8, 10-11, 12 and 31*

As indicated above, claims 1, 2, 4, 6, 10-11 and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Jackson in view of Miskew. Independent claim 1 recites, among other features and elements, “a second hook . . . comprising a second internal surface having a curved portion including a ridge extending along said curved portion in a direction from the first end to the second end . . . .” The outstanding Office Action indicates that Jackson fails to disclose this feature. (See page 5; line 16 to page 6, line 5). However, the Office Action asserts that “[i]t would have been obvious . . . to have substituted the thread mechanism disclosed by Jackson with the ridge mechanism disclosed by Miskew, in order to achieve the predictable result of providing stability to the construct.” (See page 6, lines 6-15). It is respectfully submitted that, when considering Jackson in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention as required by the Manual of Patent Examining Procedure (MPEP) §2141.02, those having skill in the art would not modify Jackson in the manner suggested by the Office Action.

Jackson discloses a cross member 5 that includes a pair of hooks 11 formed on opposite ends of a link 10. Each hook 11 includes a curved section 14 which has “an inner surface which is sized and shaped to closely contact and tightly abut against an outer surface 18 of a rod 4 in at least partially surrounding relation.” (See column 5, lines 23-36; emphasis added). Jackson also

discloses a set screw 1 that includes a mounting segment 25 and a rod engaging segment 27 that engages the rod 4 to prevent the rod from rotating about its axis within rod receiving opening 20. (See column 5, lines 44-48 and 54; and column 6, line 5). Engagement between the segment 27 and the rod 4 urges a portion of the surface 18 of the rod 4 into frictional engagement with the inner surface 16 of the opening 20, which “. . . resists linear displacements of the rod 4 relative to the cross member 5, as well as angular or radial displacements”. (See column 6, lines 9-11; emphasis added). With regard to Miskew, this reference discloses an elongated threaded rod 72 which includes a plurality of hooks 74. Each of the hooks 74 includes “. . . a knife edge 78 inside the hook to achieve more secure hooking to the individual vertebra.” (See column 6, lines 34-37). Notably, the hook 74 is specifically configured to bite into and engage vertebral bone via the knife edge 78, and not to clampingly engage a spinal rod. As illustrated in Figure 6 of Miskew, a pair of linear segments angularly extends from the interior mid-portion of the curved section of the hook 74 toward one another and converge to define a sharp point that defines the knife edge 78. Moreover, as illustrated in Figure 5 of Miskew, the knife edge 78 extends beyond the interior portion of the curved section of hook 74.

When considering the emphasis Jackson places on the interaction and secure engagement between the set screw 1 and the rod 4, those skilled in the art would not substitute the set screw 1 for the knife edge 78, as suggested by the Office Action. Indeed, such substitution would eliminate some of the functional aspects provided by the set screw 1 which are repeatedly mentioned in Jackson. For example, substituting the set screw 1 of Jackson with the knife edge 78 would not resist/prevent rotation of the rod 4 within the rod receiving opening 20, as specifically taught by Jackson. Accordingly, those skilled in the art would be further lead away from the modification suggested by the Office Action.

Additionally, when considering Jackson in its entirety, those skilled in the art would not modify the connector 5 to include the knife edge 78 in combination with the set screw 1. For example, if Jackson were modified to include the knife edge 78 disclosed by Miskew, the inner section 16 of the curved portion 14 of the hook 11 would no longer be shaped to closely contact and tightly abut against the outer surface 18 of rod 4 (as explicitly taught by Jackson and discussed above). Instead, only the pointed end of the knife edge 78 would contact the outer surface 18 of the rod 4, which would lead to instability and non-secure engagement between the

rod and the connector hook. As a corollary, the possibility of the rod 4 being angularly displaced relative to the cross member 5, an occurrence Jackson specifically teaches is undesirable (see above), would be increased. Therefore, the Applicant respectfully submits that Jackson clearly teaches away from adding a knife edge 78 to an inner surface of the connector hook, and those skilled in the art would be dissuaded from doing so. Furthermore, as indicated above, the hook 74 of Miskew is specifically configured to bite into and engage vertebral bone via the knife edge 78, and not to clampingly engage a spinal rod.

In view of the foregoing, the Applicant respectfully submits that a *prima facie* case of obviousness has not been established with regard to independent claim 1. Accordingly, withdrawal of the rejection of independent claim 1 in view of the Jackson/Miskew combination and allowance of same are respectfully requested. Each of claims 2, 4, 6 and 10-11 and 31 depends from independent base claim 1 or an intervening claim, and is patentable over the Jackson/Miskew combination for at least the reasons supporting the patentability of independent base claim 1.

Claims 3 and 5 depend from independent base claim 1 or an intervening claim, and stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson/Miskew/Lombardo combination. The addition of Lombardo does not overcome the above-mentioned deficiencies of the Jackson/Miskew combination with respect to the rejection of independent claim 1. Accordingly, claims 3 and 5 are patentable over the Jackson/Miskew/Lombardo combination for at least the reasons supporting the patentability of independent claim 1.

Claims 7 and 8 depend from independent base claim 1 or an intervening claim, and stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson/Miskew combination in further view of the '523 patent. The '523 patent does not overcome the above-mentioned deficiencies of the Jackson/Miskew combination with respect to the rejection of independent claim 1. Accordingly, claims 7 and 8 are patentable over this combination of references for at least the reasons supporting the patentability of independent claim 1.

Claim 12 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson/Miskew combination. Claim 12 is directed to a method of treating a spinal deformity that includes, among other features, "... providing an apparatus according to claim 1". For at



least the reasons discussed above in support of the patentability of independent claim 1, the Applicant submits that claim 12 is patentable for at least these reasons as well.

**Independent Claim 13 and Dependent Claims 14-18, 21 and 32**

Claims 13-16, 21 and 32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson/Miskew combination. Independent claim 13 is directed to an apparatus and recites, among other elements and features, “a second hook . . . comprising a second internal surface wherein the second internal surface curves both in a first direction from the shaft to the second end and in a second direction oblique to the first direction, wherein said curves in said first and second directions are overlapping and intersecting . . . .” For reasons similar to those discussed above in support of the patentability of independent claim 1, those skilled in the art would not modify Jackson in view of Miskew to arrive at the invention recited in independent claim 13.

However, further reasons support the patentability of independent claim 13. With regard to Miskew, as indicated above, a pair of linear segments angularly extends from the interior portion of the curved section of hook 74 toward each other to a sharp point that defines a knife edge 78. Contrary to the assertion set forth on page 6 of the Office Action, the linear segments of knife edge 78 do not “. . . produce curves that arch in an oblique direction relative to the curve of the hook . . . .”. Indeed, as clearly shown in Figure 6 of Miskew, the linear edges defining the pointed knife edge 78 are not in any way “curved” and do not “arch” in any direction. As a corollary, the Jackson/Miskew combination fails to disclose a second internal surface that curves both in a first direction from the shaft to the second end and in a second direction oblique to the first direction, as recited in independent claim 13.

In view of the foregoing, independent claim 13 is submitted to be patentable over the cited references, and allowance of same is respectfully requested. Each of claims 14-18, 21 and 32 depends from independent base claim 13 or an intervening claim and is patentable over the Jackson/Miskew combination for at least the reasons supporting the patentability of independent base claim 13.

Claims 17 and 18 depend from independent base claim 13 or an intervening claim and stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson/Miskew

combination in further view of the '523 patent. The '523 patent does not overcome the above-mentioned deficiencies of the Jackson/Miskew combination with respect to the rejection of independent claim 13. Accordingly, claims 17 and 18 are patentable over this combination of references for at least the reasons supporting the patentability of independent base claim 13.

### **Independent Claim 33**

As indicated above, it is believed that independent claim 33 also stands rejected in view of the Jackson/Miskew combination. Independent claim 33 is directed to an apparatus and recites, among other features and elements, “a second hook portion . . . comprising a second internal surface having a curved portion including a saddle extending along said curved portion in a direction from said first end to said second end . . . .” For at least the reasons discussed above with respect to independent claims 1 and 13, it is respectfully submitted that those skilled in the art would not modify Jackson in view of Miskew to arrive at the invention recited in independent claim 33. Notably, independent claim 33 recites “a curved portion” which includes “a saddle extending along said curved portion in a direction from said first end to said second end”. The Applicant submits that the pointed knife edge 78 fails to satisfy these features. Accordingly, withdrawal of this rejection and allowance of independent claim 33 are respectfully requested.

### **New Claims 34-38**

New claims 34-38 have been added in this response. Support for these claims may be found, for example, in Figures 26-27 and on page 24, lines 6-7 of the written description of the subject application. Each of claims 34-38 depends from a respective one of the independent base claims 1, 13 and 33 or an intervening claim, and is submitted to be patentable for at least the reasons supporting patentability of their respective base claims, although further reasons support the patentability of these claims.

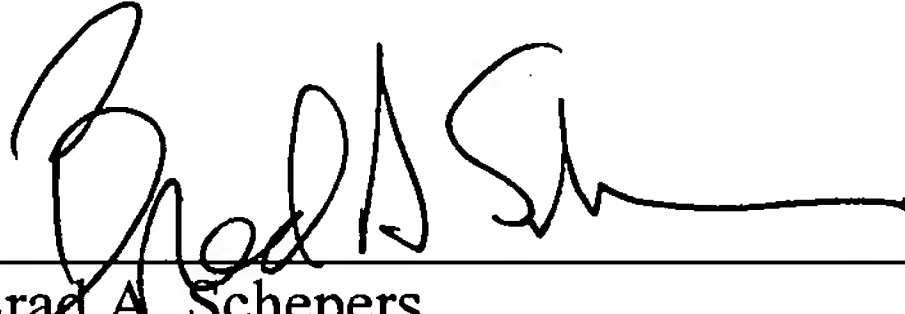
For example, claim 34 depends from independent base claim 1 and recites “wherein said curved portion curves in a second direction extending obliquely to and intersecting said ridge.” Claim 35 further recites “wherein said curved portion curves in said second direction from a first lateral edge of said second hook to a second lateral edge of said second hook.” Claim 36 depends from independent claim 13 and recites subject matter similar to that recited in claims 34

and 35. Additionally, claims 36 and 37 depend from independent claim 33 and recite subject matter similar to that recited in claims 34 and 35. As discussed above with respect to independent claim 13, Miskew does not disclose a curved portion that curves in more than one direction, but instead includes a pointed knife edge 78 defined by linear surfaces that converge at a point. Furthermore, as illustrated in Figure 6 of Miskew, the linear segments that define the knife edge 78 do not extend from a first lateral edge to a second lateral edge of hook 74. Instead, these linear segments are positioned in the middle portion of the hook 74.

### CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance with pending claims 1-5, 7-8, 10-18, 21 and 31-38. Reconsideration of the present application is respectfully requested. Timely action towards a Notice of Allowance is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the present application.

Respectfully submitted,

By:   
Brad A. Schepers,  
Reg. No. 45,431  
Krieg DeVault LLP  
One Indiana Square, Suite 2800  
Indianapolis, IN 46204-2079  
(317) 238-6334